STATEMENT

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In Opposition to Connecticut House Bill 7174
February 28, 2018

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully opposes House Bill 7174, which includes a number of unnecessary provisions that raise significant legal concerns and will not help patients.

Discussions about the cost and affordability of medicines are important. No patient should have to worry about whether they can afford the health care they need. Just last year, Connecticut passed first-in-the-nation legislation that takes an important step toward examining and addressing cost and affordability concerns throughout the entire supply chain. HB 7174 ignores those recent efforts and proposes a number of concerning provisions that raise legal and safety concerns, ignore the unique needs of patients, and may have the unintended consequence of delaying generic market entry. For the reasons detailed below, PhRMA urges legislators to oppose HB 7174.

Provisions in this legislation related to patent settlement agreements intrude on the province of the Federal Trade Commission and the federal courts, raise significant legal concerns, and are unnecessary.

House Bill 7174 seeks to inject state authority into patent settlement agreements by requiring notice of certain agreements be provided to the Insurance Department and then imposing price control reductions for branded medications subject to such agreements. This not only raises significant legal concerns but could have the unintended effect of delaying generic market entry. Limiting patent settlements could result in delayed entry of generics, substantial litigation costs, and business uncertainty for both innovator and generic companies. Patent settlements are an expected result of the framework that Congress created in the Hatch-Waxman Act to resolve patent disputes. They do not extend the patent term of an innovator's drug, but rather, they generally permit generic drugs on the market earlier than patent expiration, generating significant savings for consumers.

This legislation would displace the Federal Trade Commission's role in policing patent settlement agreements and is inconsistent with the approach of the U.S. Supreme Court in *FTC v. Actavis*,[1] which established the standard under which the FTC and courts review these

[1] 133 S. Ct. 2223 (2013)

agreements. The FTC has the ability to review and take enforcement action against individual patent settlements under the U.S. Supreme Court's holding in *Actavis* using a "rule of reason" to determine whether a patent settlement agreement is anticompetitive. Since 2003, Congress has required pharmaceutical manufacturers to submit to the FTC certain agreements between manufacturers of new drugs and generic products. State legislation is not needed due to the existence of the comprehensive federal frameworks governing the resolution of patent disputes concerning generic drugs and review of patent settlement agreements.

House Bill 7174's price reduction triggers are intended effectively to negate certain market entry agreements between brand manufacturers and generic competitors by nullifying the benefit of such agreements and actively penalize the brand manufacturer for entering into such agreements. Such a substantial impairment on manufacturers' right of contract raises serious concerns of state over-reach and intrusion into the private marketplace.

The over-reach of the state into these national agreements raises Dormant Commerce Clause concerns and is not limited to manufacturer contracts with generic competitors. The proposed law would also impose significant impairments on a broad range of other contracts across the entire health industry—including contracts between manufacturers and carriers, manufacturers and PBMs, and potentially contracts between carriers and beneficiaries could all be substantially impaired.

Further, under the Supremacy Clause of the U.S. Constitution, state laws are preempted when they conflict with federal laws and objectives. Federal courts have held that state price control laws targeting patented prescription drugs are preempted by federal patent law.[2]

The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes state-based prescription drug importation programs because such proposals falsely characterize importation as a way to lower drug costs and ignore the unavoidable threats to patient safety that would result.

Due to the U.S. Food and Drug Administration's (FDA) comprehensive drug approval process, medicines on the U.S. market are widely regarded as the safest in the world. The U.S.'s closed distribution system plays a critical role in helping to keep the global proliferation of counterfeit medicines from infiltrating the U.S. prescription medicine system. An importation program would jeopardize the integrity of our current distribution system and as a result, the safety of American consumers.

Even if the HHS Secretary makes the required certification to Congress, it is then the FDA who is charged with promulgating rules to implement a national allowance of imported drugs from Canada. In March 2017, a bipartisan group of former FDA Commissioners sent a letter to Congress opposing importation from Canada. Among their reasons for opposition, the Commissioners cited serious risks to patients and consumers and an increased likelihood that

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[2] *See BIO and PhRMA v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007).

drugs purchased from foreign countries may be substandard, unsafe, adulterated, or fake. The letter further stated the FDA lacks the resources needed to oversee an importation program.[3]

In addition to the FDA, Canadian authorities have stated that they are not responsible for the safety and quality of prescription drugs exported from Canada into the United States.[4] Canadian law does not prohibit the transshipment of drugs from any country—including the developing world—into Canada and then into the United States, exacerbating concerns about the safety and reliability of these medicines. Dr. Robert Califf, former Commissioner of the FDA recently stated, "FDA evaluation of non- FDA-approved imported drugs revealed that while nearly half of imported drugs claimed to be Canadian or from Canadian pharmacies, 85 percent of such drugs were actually from different countries." Although proposed state importation programs require regulators to "sample imported drugs for purity, chemical composition, and potency to the extent required by federal law," former Food and Drug Administration (FDA) commissioners have stated, "even if spot-checking discovered a dangerous or counterfeit product, in the absence of the closed system currently in use, there would be no way to trace that product to its origin or intervene to protect other consumers before irreparable harm occurs.[5]"

PhRMA expresses concern about the design of the Connecticut Prescription Drug Program as the scope of the program and the benefit design to be developed by the Comptroller is unclear.

As drafted, the proposed Connecticut Prescription Drug Program ("Program") appears to be geared toward individual residents of the state in an effort to establish a bulk purchasing program and centralized benefit design. The scope of individuals eligible to participate, and how the Program would interface with the Comptroller's authority to administer the state employee benefit – and corresponding expansion of that program to include self-insured private businesses as proposed by this bill – is unclear.

Prescription medicines have transformed the trajectory of many debilitating diseases and conditions, including HIV/AIDS, cancer, and heart disease, resulting in decreased death rates, improved health outcomes, and better quality of life for patients. Better use of Medicines could eliminate up to $213 billion in US health care costs annually, which represents 8% of the nation's health care spending.[6] Better use of medicine yields significant health gains by avoiding the need for other, more costly, medical services. PhRMA appreciates efforts to ensure access to medicines and is happy to be part of a conversation as to how best to serve patients.

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[3] McGinley, L. Four former FDA commissioners denounce drug importation, citing dangers to consumers. Washington Post. March 17, 2017. https://www.washingtonpost.com/news/to-your-health/wp/2017/03/17/four-former-fda-commissioners-denounce-drug-importation-citing-dangers-to-consumers/?utm_term=.7be381f7d329

[4] HHS Task Force Report citing Letter from Diane C. Gorman, Assistant Deputy Minister, Health Canada, to Richard H. Carmona, U.S. Surgeon General, pg. 60-61. June 1, 2004

[5] McGinley, L (see footnote 3)

[6] IMS Institute for Health Care Informatics

Given the variability in the medical needs of a population of individuals, a list of preferred drugs cannot be a "one-size-fits-all" product, such as that which results from a bulk purchasing program. It is important for patients with differing needs to have a choice of health plans, each of which has its own formulary and process for meeting the needs of individuals for whom it is accountable. Any benefit design under the proposed Connecticut Prescription Drug Program should include flexibility and critical patient protections that ensure participants are able to access the right drug at the right time.